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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/755,392

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Roel Otto

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OLIFF & BERRIDGE, PLC
P.O. BOX 19928
ALEXANDRIA, VA 22320

EXAMINER

BARNHART, LORA ELIZABETH

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 03/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/755,392	Applicant(s) OTTO, ROEL	
	Examiner Lora E Bamhart	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 March 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Specification

The examiner notes that the specification has been amended to clarify the use of trademarks, to provide legible copies of the tables, and to provide a substitute abstract. The first Office action maintained that the term "minimal medium" is confusing, as this term is not clearly defined within the specification. The examiner regrets that Table 3 was erroneously referenced in this objection; clearly, Table 2, not Table 3, refers to a "minimal medium".

In the first Office action, the examiner queried the example at page 16, stating that said example does not clarify whether yeast extract is required for fermentation of lactic acid from xylose. In the reply filed 3/8/05, the applicant asserts that the person of ordinary skill in the art would have known from the description provided that said yeast extract is added merely to increase the biomass and is not necessary for aiding in the conversion of xylose to lactic acid. The examiner disagrees. The phrasing of the example at page 16, lines 1-13, implies that several events occur in a specific order:

1. *B. coagulans* DSM 2314 is grown on xylose-containing minimal medium.
2. Yeast extract is added during the fermentation.
3. Xylose is depleted from the media and converted mostly to lactic acid.

The example as presented gives no indication as to whether the addition of yeast extract is required for the growth or fermentation of *B. coagulans* DSM 2314. This

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objection to the specification is maintained, as no evidence is presented to indicate to the person of ordinary skill in the art that yeast extract is not required for production of lactic acid from xylose. For this reason, Table 2 is unclear because it recites the use of a "minimal medium", but the sole example provided recites the use of minimal medium to which yeast extract has been added (page 16). Minimal medium is defined at page 8, line 20-page 9, line 2, and is not disclosed as comprising yeast extract. Clarification is required. The objection to the specification is maintained.

Claim Rejections - 35 USC § 112

Amended claims 7, 9, and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 is confusing in that it recites separating the lactic acid and/or lactate from "a fermentation broth", but no broth of any kind is recited in parent claim 1. It is not clear to which broth the claim refers, or how said broth is related to the instantly claimed process. Clarification is required. Because claims 9 and 10 depend from indefinite claim 7 and do not clarify the point of confusion, they must also be rejected under 35 U.S.C. 112, second paragraph.

Claims 9 and 10 are confusing in that they recite "subjecting the lactic acid and/or lactate to one or more purification steps after separating the lactic acid and/or lactate from the fermentation broth, wherein the moderately thermophilic *Bacillus* species is grown on a chemically defined medium". It is not clear whether the "wherein" phrase

refers to the purification step, the separation step, or to some undefined step.

Clarification is required.

Claim Rejections - 35 USC § 102

Claims 1-5 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Payot et al. taken in light of Godshall et al., cited in prior action. The claims are drawn to a process for the preparation of lactic acid or lactate comprising homolactically and anaerobically fermenting a pentose-containing substrate by a moderately thermophilic *Bacillus* species. In some dependent claims, said substrate comprises a specific monosaccharide. In some dependent claims, the *Bacillus* biomass is separated from the broth in which fermentation occurred.

As detailed in the Office action mailed 11/4/04, Payot et al. teach a process for using *B. coagulans* TB/04, a homofermentative lactic acid bacterium (Payot et al., page 192, column 1, paragraph 2) to ferment lactic acid and/or lactate from molasses. Payot et al. further teach separating the biomass from the culture medium (Figure 8) and separating lactic acid from the culture medium using HPLC (page 192). Godshall et al. was cited as evidence that molasses comprises glucose, xylose, and arabinose (Tables 3 and 4). Applicant's arguments filed 3/8/05 have been fully considered but they are not persuasive for the following reasons.

The basis of the applicant's arguments lies in the teachings of Godshall et al. regarding the components of molasses. In the first Office action, the examiner asserted that since Godshall et al. teach that molasses comprises arabinose, xylose, and glucose (e.g., Table 4, bottom row), the fermentation of lactic acid from molasses of Payot et al.

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includes fermentation of pentoses. Applicants traverse this assertion on the basis that Godshall et al. teach that molasses contains macromolecules, i.e. polysaccharides, that themselves contain the monosaccharides of claims 2, 4, and 5, not the monosaccharides themselves. Applicants also assert that molasses does not, in fact, comprise any pentoses, based on information from the United States Sugar Corporation. These arguments are not found persuasive for the following reasons.

The language of the claims, as discussed in the first Office action, is open; that is, claim 1 is drawn to preparation of lactic acid or lactate from a substrate containing pentoses in any form. The transitional term "comprising", which is synonymous with "including," "containing," or "characterized by," is inclusive (or open-ended) and does not exclude additional, unrecited elements or method steps. See, e.g., *Invitrogen Corp. v. Biocrest Mfg., L.P.*, 327 F.3d 1364, 1368, 66 USPQ2d 1631, 1634 (Fed. Cir. 2003). The claims do not recite, require, or suggest that the claimed pentoses be in their monomer form; on the contrary, the language of the claims includes any composition with any number or character of constituents, so long as at least one pentose is present.

Similarly, the information from the U.S. Sugar Corporation is not found to be convincing as it pertains to the pentose composition of molasses. The examiner agrees that the document indicates that molasses comprises sucrose, fructose, and glucose. Nowhere in the document, however, is presented any evidence that pentoses were assayed in the molasses sample in question and found to be lacking. The document provides no substantive evidence as to the complete composition of molasses, but

rather gives evidence of the prevalence of specific components of particular interest to the U.S. Sugar Corporation.

Claim Rejections - 35 USC § 103

Claims 1-5 and 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over PCT '601 taken in view of Payot et al. and Godshall et al., cited in prior action. The claims are drawn to a process as described above. In some dependent claims, the lactic acid and/or lactate are separated from the broth in which fermentation occurred.

As detailed in the Office action mailed 11/4/04, PCT '601 teaches a process for using *B. coagulans* J44 and *B. smithii* J30 to ferment lactic acid from a chemically defined medium comprising glucose, xylose, and arabinose under microaerophilic conditions (pages 7-10). PCT '601 does not teach separation steps for the biomass or the produced lactic acid, or production of lactic acid under anaerobic conditions. Payot et al. teach that at pH 6.4, *B. coagulans* TB/04 produces twice as much lactic acid under anaerobic conditions as that produced under aerobic conditions (Table 5). Payot et al. further teach methods for separating biomass and lactic acid from the other components of the fermentation mixture (Figure 8 and page 192). Godshall et al. teach the components of molasses, which include pentoses (Tables 3 and 4).

Applicant has traversed this rejection on the basis that PCT '601 does not teach or suggest fermenting lactic acid from pentose-containing substrates under anaerobic conditions using *Bacillus* species. This argument is not found persuasive because one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208

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USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicant further traverses the examiner's assertion that Payot et al. teaches anaerobic fermentation of lactic acid. Applicants assert that Payot et al. teach an increase in biomass with aerobic fermentation, but that Payot et al. do not teach anaerobic fermentation. This argument is not found to be persuasive. In fact, later in the same sentence as that referred by applicants, Payot et al. teach that the concentration of lactic acid is "dramatically decreased" under aerobic conditions, implying that anaerobic conditions are actually preferred for fermentation of lactic acid.

Applicant's remaining arguments are based on the pentose composition of molasses and are not found to be persuasive for those reasons already stated above.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over PCT '601 taken in view of Payot et al. and Godshall et al. as applied to claims 1-5 and 7-9 above, and further in view of U.S. '477. Claim 6 is drawn to a process as described above, in which the fermenting is carried out by a mixture of a moderately thermophilic *Bacillus* species and another lactic acid-producing microorganism.

Applicant has traversed this rejection on the basis that neither PCT '601 nor Payot et al. teach or suggest anaerobic fermentation of pentose-containing substrate, which is not found to be persuasive for the reasons detailed above.

Applicant further traverses this rejection on the basis that U.S. '477 does not teach or suggest fermenting lactic acid from pentose-containing substrates under anaerobic conditions. This argument is not found persuasive because one cannot show

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nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller* (citations *supra.*).

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over PCT '601 taken in view of Payot et al. and Godshall et al. as applied to claims 1-5 and 7-9 above, and further in view of U.S. '881. Claim 10 is drawn to a process as described above, in which the produced lactic acid or lactate is further purified after being separated from the broth in which fermentation has occurred.

Applicant has traversed this rejection on the basis that neither PCT '601 nor Payot et al. teach or suggest anaerobic fermentation of pentose-containing substrate, which is not found to be persuasive for the reasons detailed above.

Applicant further traverses this rejection on the basis that U.S. '881 does not teach or suggest fermenting lactic acid from pentose-containing substrates under anaerobic conditions. This argument is not found persuasive because one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller* (citations *supra.*).

Applicant further traverses the rejection on the basis that U.S. '881 teaches anaerobic fermentation of lactic acid from a glucose-containing substrate and the subsequent purification of lactic acid therefrom. This argument was not found to be persuasive because U.S. '881 is relied upon solely for its teachings regarding purification of lactic acid from a broth in which fermentation has occurred. The method of making said lactic acid is irrelevant; the teachings of U.S. '881 are applicable to purification of lactic acid from any broth.

No claims are allowed. No claims are free of the art.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lora E Barnhart whose telephone number is 571-272-1928. The examiner can normally be reached on Monday-Friday, 8:00am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lora E Barnhart

WB

Irene Marx

**IRENE MARX
PRIMARY EXAMINER**